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ABSTRACT

This report provides administrators, project leaders, and researchers with information about major federal regulations governing research in the social sciences. The report is presented in five major chapters. Chapter I identifies the report's limitations. For example, it describes only statutory and regulatory provisions and covers only domestic research issues. Chapter II reviews the Federal Reports Act which governs the process of information creation and collection by federal agencies. Two sections discuss the Act's ramifications for research sponsored by executive federal agencies and by independent federal regulatory agencies. Chapter III summarizes regulations protecting the human subject during data collection. It specifically focuses on issues of human subjects at risk, informed consent, prisoner research, research involving children, and educational and social science research. Regulations concerning storage and disclosure of data are reviewed in chapter IV. These regulations include the Privacy Act of 1974, the Freedom of Information Act, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act. Chapter V reviews sanctions for non-compliance under the Federal Reports Act, the Privacy Act of 1974, alcohol abuse research, Department of Health, Education, and Welfare human subject regulations, and research sponsored by the Law Enforcement Assistance Administration. (AV)

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MAJOR FEDERAL REGULATIONS GOVERNING SOCIAL SCIENCE RESEARCH

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PREFACE

This report provides administrators, project leaders, and researchers with background on the major federal regulations governing research in the social sciences. It is intended to be helpful in establishing policy and procedures within a contractor's facility as well as to help those concerned with detailed exploration of the regulations applicable to specific grants or contracts.

Research organizations and researchers within these organizations have increasingly had to contend with federal regulations that do not originate from any one source, are not all clearly interrelated, and do not appear to have a common governmental objective. Instead, they may seem a hindrance. Researchers may not be aware of regulations that govern their research; moreover, some regulations may apply to some activities and not to others—which may create confusion and engender feelings of inequitable treatment. This report sorts out the various major regulations in an effort to reduce this confusion.

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Full responsibility for any errors of fact or interpretation lies with me alone.

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I. INTRODUCTION

Social science research rarely involves physically intrusive biomedical procedures. It primarily uses information gathered from surveys, interventions, demonstrations, model programs, and responses to the introduction of stimuli. Consequently, regulating social science research means regulating information at the various stages of collection, storage, manipulation, and disclosure. In addition, some regulations touch upon several stages of the information process, creating a potentially confusing overlap, some affect only a federal agency, and others affect organizations and individuals doing research with that agency.

This report has several limitations. First, the subject area is vast and the perspective broad. No claim is made that the statutes and regulations exhaust those applicable to social science research undertaken by federal contractors. Undoubtedly there are other regulations, and further research might uncover new areas. For example, although the Office of Management and Budget (OMB) has published guidelines for the Privacy Act, every federal agency will publish implementing regulations. The Privacy Act discussion deals only with HEW because HEW funds a large amount of social science research. Second, the report describes only the statutory and regulatory provisions because a broader scope would have been inappropriate.[1] Third, my intent was to cover the federal regulation of "domestic" research information; consequently, this report may not be applicable to national security social science research. Finally, I attempted to point out major rules and regulations with which a researcher should be familiar, rather than to state the precise law.

[1] See B. S. DuVal, Jr., "Educational Research and the Protection of Human Subjects," *American Bar Foundation Research Journal*, No. 2, 1977, pp. 477-514, for an informative discussion of and further references to cases involving civil suits for damages resulting from psychological distress, invasion of privacy, and inadequate informed consent.

II. REGULATING THE COLLECTION OF DATA: THE FEDERAL REPORTS ACT

Research undertaken by *contract or grant* for a federal agency, or research undertaken by the federal agency itself, involving the collection of information from individuals may require compliance with 44 U.S.C. § § 3501–3512.

Because those sections provide for divided jurisdiction, researchers should first categorize the type of agency for which the research is being conducted. Section 3509 gives the Director of the OMB jurisdiction over the regulation of data collected by the executive federal agencies.[1] Section 3512, adopted in 1974, gives the Comptroller-General, GAO, jurisdiction over the regulation of data collected by independent federal regulatory agencies.[2]

Despite the jurisdictional division, the purpose and objectives and the resulting form of regulation are similar. The purpose is to assure that information federal agencies require is obtained with a minimum burden upon business enterprises and "other persons required to furnish information." The objectives originally were to avoid unnecessary duplication of effort and to assure that the information collected is tabulated to maximize its usefulness to other federal agencies and to the public.[3]

The OMB and GAO have great power to protect privacy through their ability to disapprove the information collection activity. Yet these sections have not generally been used to protect privacy because their primary statutory objectives were to improve efficiency, minimize the burden on those supplying information, and reduce the costs of collecting information.[4] However, the regulations have recently been modified to reflect concerns with the Privacy Act of 1974 and the Freedom of Information Act.[5]

RESEARCH SPONSORED BY EXECUTIVE FEDERAL AGENCIES [6]

Section 3509 of the Federal Reports Act states that a federal agency may not

[1] Additional authority is provided by 31 U.S.C. § 18b, which authorizes and directs the President, through the OMB Director, to "issue regulations and orders for the improved gathering, compiling, analyzing, publishing, and disseminating of statistical information for any purpose by the various agencies in the executive branch."

[2] Civil Aeronautics Board, Commodity Futures Trading Commission, Consumer Product Safety Commission, Equal Employment Opportunity Commission, Federal Communications Commission, Federal Energy Administration, Federal Maritime Commission, Federal Power Commission, Federal Trade Commission, Interstate Commerce Commission, National Labor Relations Board, Nuclear Regulatory Commission, Securities and Exchange Commission.

[3] See 44 U.S.C. § 3501 for the executive federal agencies and 4 C.F.R. § 10.3(a) (1977) for the independent federal regulatory agencies.

[4] K. Greenawalt, *Legal Protections of Privacy*, Final Report to the Office of Telecommunications Policy, Executive Office of the President, 1975, p. 109.

[5] Transmittal Memorandum No. 1 to the Heads of Executive Departments and Establishments from James Lynn, OMB Director, regarding the Revision of Attachment A to Circular No. A-40, February 10, 1976.

[6] The collection of information by executive federal agencies is governed by the Federal Reports Act, 44 U.S.C. § § 3501–3511; OMB Circular No. A-40, May 3, 1973; Attachment A to Circular No. A-40, Revised, February 10, 1976; Attachment B to Circular No. A-40, Revised, February 10, 1976; and Supplemental Instructions for Completion of Standard Form 83, "Clearance Request and Notice of Action," March 2, 1976.

conduct or *sponsor* the collection of "information upon identical items, from ten or more persons, other than federal employees," unless it submits, in advance, the plans and forms to the Director of OMB and he does not disapprove.

For purposes of the Act, "person" means an individual, partnership, association, corporation, business trust, legal representative, an organized group of persons, a state or territorial government or branch, or a political subdivision of a state or territory or a branch of a political subdivision. "Information" means facts obtained or solicited by the use of written report forms, application forms, schedules, questionnaires, or other similar methods calling for answers to identical questions from ten or more persons, other than agencies, instrumentalities, or employees of the United States (44 U.S.C. § 3502).

Before *adoption* or *revision* of any plans or forms to be used in the collection, the federal agency conducting or sponsoring the research must submit "to the Director the plans or forms, together with copies of pertinent regulations and of other related materials as the Director ... has specified."

Thus, a research project must comply with this Act only if *all* the following conditions are met:

(1) The information collection is sponsored by a federal agency.
(2) The information collection is of identical items.
(3) The information will be collected from ten or more persons.
(4) The information is not being collected solely from federal employees.

Whether a federal agency is deemed to have "sponsored" the collection of information depends on whether a contractor or a recipient of a grant does the collecting. A plan or report form used by a contractor is deemed to be sponsored by the agency that awards the contract, *except* when the data collection is neither required nor implied by the terms of the contract *and* no representation of federal sponsorship or association is made to the respondents.

A plan or report form used by a recipient of a federal grant is *not* deemed to be sponsored by an agency, *except* when: (1) the recipient of a grant represents to respondents that the information is being collected for or in association with a federal agency; (2) the recipient of the grant uses the plan or report form to collect information that the agency has requested for the planning, operation, or evaluation of its program; or (3) the terms and conditions of the grant provide for the agency to approve the survey design, questionnaire content, or data collection procedures; or (4) the terms and conditions of the grant provide for either submission of the data for individual respondents to the agency or the preparation and submission of tabulations requested by the agency.

There may be sponsorship even though there is no contract or grant. When a federal agency requests a person or organization to collect specific information to be made available to the agency, the plan or report form or the part used to collect this information must be regarded as sponsored.

Because the Act applies to information collection *"from* ten or more persons," it could be argued that information *about* ten or more persons is a different matter. The distinction is that the first level, a personal interview or questionnaire, is information *from* a person. But if someone else had already collected that information and the researcher collected identical items *about* ten or more persons from a central file, then arguably the latter is not within the purview of the Act. This

assumes that the researcher collects his own information or requests information from fewer than ten central files under separate organizational control. Otherwise if ten or more organizations (considered persons under the Act) are requested information about persons in their files, the information-gathering activities are under the Act's purview.

If the research is considered sponsored by a federal agency and involves the collection of identical items from ten or more persons, it may still be possible to avoid having to await OMB approval. OMB Circular No. A-40, Attachment A, exempts forms and reporting requirements from the requirement of approval if the collection of information (1) is for identification or classification in connection with laboratory research and clinical investigations; or (2) is done through tests or examinations to determine a person's knowledge, abilities, or aptitudes. (The collection of information for identification or classification in connection with such tests is also exempted.)

Finally, the requirements of submission of plans or forms and approval requests are imposed upon the federal agency, not the sponsored researcher. Presumably, the agency will require the sponsored researcher to submit his plans and forms as a step in the process of obtaining OMB approval. The agency will inform the researcher of the requirements of Attachment A; it will ensure that Standard Form 83, "Clearance Request and Notice of Action," is submitted; and it will ensure that the plan or report form is not used without prior clearance.

RESEARCH SPONSORED BY INDEPENDENT FEDERAL REGULATORY AGENCIES [7]

Through § 3512, the Comptroller-General has jurisdiction over the independent federal regulatory agencies' information collection activities. In most other respects, the regulation is similar to that of the executive federal agencies. However, a few provisions have important differences.

An independent regulatory agency shall not conduct or sponsor information collection upon an identical item from ten or more persons, other than federal employees, unless, in advance of adoption or revision of any plans or forms to be used in the collection (1) the agency has submitted the plans or forms together with the copies of the pertinent regulation to the Comptroller-General, and (2) the Comptroller-General has advised that the information is not available to the independent agency from another source within the federal government.[8]

The major difference is that the independent regulatory agency does not need *approval* to collect the information. It only needs to submit the plans or forms to be used. In addition, the independent regulatory agency is only seeking the Comptroller-General's *advice*. This difference is emphasized in § 3512(d), which states, "the independent regulatory agency shall make the final determination as to the necessity of the information in carrying out its statutory responsibilities." Furthermore, the Comptroller-General must render his advice within 45 days of the request. If he does not, the regulatory agency may proceed to obtain such informa-

[7] The collection of information by the independent federal regulatory agencies is governed by 44 U.S.C. § 3512 and the regulations appearing in 4 C.F.R. Part 10 (1977).

[8] 44 U.S.C. § 3512(c).

tion. Such collection, however, may not continue for more than one year from the date on which it commenced.[9]

Sponsorship is also defined differently for the independent regulatory agency. An agency is considered to "sponsor" the collection of information when it requires a person or organization, including its *contractor* or *grantee*, to collect specific information to be made available to the agency.

Even if the research is considered sponsored by the agency and involves the collection of information from ten or more persons, some social science research activities may still avoid having to submit the plans and forms and seeking the Comptroller-General's advice if those activities fall within the specified exemptions.[10] Exempted are (1) the collection of information for identification or classification in connection with laboratory research and clinical investigations; (2) tests or examinations given individuals to determine knowledge, abilities, or aptitudes or the collection of information for identification or classification in connection with such tests; and (3) surveys, pretests, and pilot tests.

Each independent regulatory agency is encouraged to use surveys, pretests, and pilot tests in developing major information collection proposals and before full-scale agency adoption of such major proposals. Not subject to GAO clearance are surveys, pretests, and pilot tests involving information collection from ten or more persons and designed to develop a major proposal by ascertaining and evaluating costs, respondent burdens, effects, utility, and similar criteria.[11]

The regulations for the executive federal agencies do not contain an explicit exemption for surveys, pretests, and pilot tests. However, there is a general exemption from the requirements for OMB approval for forms and reports that "do not call for information of substantial volume or importance."[12] Surveys, pretests, and pilot tests could easily fall under this exemption.

The responsibility for compliance with the Comptroller-General's regulations rests with the independent federal agencies. As a first step in the process of obtaining GAO clearance, those agencies may specify procedures and requirements for the contractor or grantee.

[9] 4 C.F.R. § 10.5(b) (1977).
[10] 4 C.F.R. § 10.6(c) (1977).
[11] 4 C.F.R. § 10.3(b) (1977).
[12] Attachment A, Circular No. A-40, Revised, Paragraph 9(f), February 10, 1976.

III. PROTECTING THE HUMAN SUBJECT DURING DATA COLLECTION

NATIONAL RESEARCH SERVICE AWARD ACT OF 1974 [1]

Popularly known as the National Research Act, this was an "Act to amend the Public Health Service Act to establish a program of National Research Awards to assure the continued excellence of biomedical and behavioral research and to provide for the protection of human subjects involved in biomedical and behavioral research and for other purposes."

Title II, § 212 (Protection of Human Subjects of Biomedical and Behavioral Research) added § 474 to the Public Health Service Act, which provides that:

(a) The Secretary [of HEW] shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(c) The Secretary of Health, Education, and Welfare shall within 240 days of the enactment of this Act promulgate such regulations as may be required to carry out Section 474(a) of the Public Health Service Act. Such regulations will apply with respect to applications for *grants* and *contracts* under such Act submitted *after* promulgation of such regulations.

This Act also created a *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, which has as one of its duties the development of guidelines to assure that biomedical and behavioral research is conducted in accordance with basic ethical principles. Another of the Commission's duties is the consideration of "mechanisms for evaluating and monitoring the performance of Institutional Review Boards ... and appropriate enforcement mechanisms for carrying out their decisions."

HEW POLICY ON THE PROTECTION OF HUMAN SUBJECTS

Although the National Research Act expressed Congressional concern for the

[1] P.L. 93-348, 88 Stat. 342, July 12, 1974.

protection of human subjects involved in research, such concern had already been evolving within HEW. Three years earlier, the *DHEW Grants Administration Manual*[2] had set forth a departmental policy on the protection of human subjects requiring, among other things, that contractors and grantees assure HEW they would comply with the Department's policy and that the institution, contractor, or grantee set up a committee to review, on a continuing basis, research involving human subjects.

In 1971, HEW issued regulations applicable to *contractors* involving research with human subjects.[3] As well as assuring compliance with HEW policy and setting up institutional review committees, the regulations required a standard "Notice to Offerors of Requirement for Adequate Assurance of Protection of Human Subjects" in all requests for proposals whose contractual performance is expected to involve risk to human subjects. In another standard clause the contractor agrees that the rights and welfare of human subjects will be protected and that the institutional review committee will annually review and approve the procedures. Further, the contractor will bear full responsibility for the performance of all work and services and will not impute any liability on the part of the government for the acts of the contractor or its employees.

Later in 1971 HEW issued *The Institutional Guide to DHEW Policy on Protection of Human Subjects.*[4] This document not only set forth HEW's policy as stated in the *Grants Administration Manual* but also interpreted HEW policy. Between 1971 and 1974 these three documents were the source of HEW's regulation of research involving human subjects.

In May of 1974, still before enactment of the National Research Act, HEW adopted more regulations protecting human subjects.[5] The regulations codified, with some changes, departmental policy set forth in Ch. 1-40 of the *DHEW Grants Administration Manual.* No research, development, or related activities supported by HEW *grant* or *contract* having human subjects should be undertaken unless a committee of the applicant or offering organization has reviewed and approved such activity and certified it to HEW. In addition, any organization receiving a *grant* or *contract* must continually review the supported activity to ensure its acceptability.

On July 12, 1974, the National Research Act was passed. On March 13, 1975, HEW made some minor technical changes in the regulations, bringing them into compliance with § 474(a) of the National Research Act.[6] The changes consisted of substituting references to "organizations" and "committees" in the earlier regulations with "institutions" and "Institutional Review Boards" in the final adopted regulations.

As things stood, the regulations were not intended to break any new ground in protecting human subjects but merely to codify existing departmental policy. The final adopted regulations, therefore, concentrated on the creation and operation of

[2] Chapter 1-40, "Protection of Human Subjects," April 15, 1971.

[3] 36 Fed. Reg. 20040 (1971). These regulations are still in effect; see 41 C.F.R. § 3-4.5500–3-4.5505 (1976).

[4] DHEW Publication No. (NIH) 72-102, December 1, 1971.

[5] 39 Fed. Reg. 18914 (1974).

[6] 40 Fed. Reg. 11854 (1975). These regulations were redesignated at 40 Fed. Reg. 33528 and may also be found at 45 C.F.R. Part 46 (1976).

the Institutional Review Boards (IRB) and on the submission of general and specific assurances to HEW by the institutions undertaking HEW research.

Subcontractors' activities are also covered by the regulations if the prime contractor obtains access to all or some of the subjects. If the subcontractor has filed a general assurance with HEW, in addition to its own review, the prime contractor or grantee may require the subcontractor to conduct an independent review and report to the prime contractor's IRB. If the subcontractor does not have a general assurance on file, HEW will require a special assurance.

Institutional Review Boards [7]

Safeguarding the rights and welfare of subjects at risk in activities supported under grants and contracts from HEW is primarily the responsibility of the institution that receives funding. HEW will require that no research be undertaken until the IRB has received and approved such research and the institution has submitted a certification of such review and approval to HEW.

The IRB is actually an outcome of the requirements for a *general assurance*, which is required from institutions having a significant number of concurrent HEW-supported projects involving human subjects. It is merely a written assurance acceptable to HEW stating that the institution will comply with HEW policy and outlining procedures for doing so.

The minimum requirements for a general assurance include:

(a) A statement of principles that will govern the institution in the discharge of its responsibilities for protecting the rights and welfare of subjects.
(b) An Institutional Review Board or Board structure that will conduct initial and continuing reviews in accordance with HEW's policy.
(c) Procedures the institution will follow in its initial and continuing review of applications, proposals, and activities.
(d) Procedures the Board will follow:

    (1) To provide advice and counsel to activity directors and investigators.
    (2) To insure prompt reporting to the Board of proposed activity changes and of unanticipated problems.
    (3) To insure that any such problems are promptly reported to HEW.

(e) Procedures the institution will follow to maintain an active and effective Board and carry out its recommendations.

The IRB shall meet the following requirements:[8]

(a) No less than five persons of varying backgrounds and sufficiently qualified through maturity, experience, and expertise to insure respect for its advice and counsel for safeguarding the rights and welfare of human sub-

[7] For general information on the performance of IRBs, see R. Cooke and A. Tannenbaum, "A Survey of Institutional Review Boards and Research Involving Human Subjects," A Report to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Survey Research Center, Institute for Social Research, University of Michigan, November 1, 1977.

[8] Proposed changes to the enumerated requirements would also require that the Board members be from diverse racial and cultural backgrounds and that no Board shall consist entirely of members of only one sex. See 43 Fed. Reg. 1050 (1978).

jects. The Board must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes.

(b) Board members shall be identified to HEW by name, earned degrees if any, position or occupation, representative capacity, and other pertinent indications of experience. Any employment or other relationship between each member and the institution must be identified.

(c) No member of the Board shall be involved in either the *initial* or *continuing review* of an activity in which he has a conflicting interest, except to provide information requested of the Board.

(d) No Board shall consist entirely of persons who are officers, employees, or agents of or are otherwise associated with the institution, apart from their membership on the Board.

(e) No Board shall consist entirely of members of a single professional group.

(f) The quorum shall be defined, but may in no event be less than a majority of the total membership.

Human Subjects at Risk

The *standards* for review by the IRB are outlined in the regulations, but the regulations are unclear on the *procedures*. An idea of what procedures would be acceptable to HEW may be obtained from HEW's interpretation of its guidelines as contained in *The Institutional Guide to DHEW Policy on Protection of Human Subjects*.

The *first step* of the review procedure is to determine whether the research activity involves human subjects to any degree. According to *The Institutional Guide*, this determination need not be made by the IRB. Rather, "in institutions with large grant and contract programs, administrative staff may be delegated the responsibility of separating those projects which do not involve human subjects in any degree."

If the research activity has human subjects, the *second step* is to determine whether they may be placed at risk. The regulations define a subject at risk as

> any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

A human subject is *not* at risk when the procedures to be applied are limited to those the committee considers established, accepted, and necessary to the *needs* of the subject. In determining what constitutes an "established and accepted method," consideration should be given to both national and local standards of practice. But even if considered established and accepted, the method may place the subject at risk if it is used for purposes other than to meet the subject's needs. If there is doubt, the project should be subject to review and approval by the institutional committee. This standard is fairly strict because it suggests close scrutiny of nontherapeutic research, but it is easy to apply because it is not difficult to determine

whether a research activity is intended solely to meet the needs of the subject. This standard could exclude a lot of research.

The second standard states that a human subject is *not* at risk if the procedures to be applied do not increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. Although this standard is more lenient, it is harder to apply because of the difficulty of determining the ordinary risks of daily life.[9]

Some risks are obvious—for example, medical and behavioral research procedures that may induce a potentially harmful altered physical state or condition. According to *The Institutional Guide*, there are also many medical, social, and behavioral projects and activities having no immediate physical risk, such as

> personality inventories, *interviews*, *questionnaires* or the use of observation, photographs, taped records or *stored data*. However, some of these procedures may involve varying degrees of discomfort, harassment, invasion of privacy, or may constitute a threat to the subject's dignity through the imposition of demeaning or dehumanizing conditions.

These projects and activities, however, raise the possibility of psychological or social injury, in which case a human subject is at risk.

Obviously, *The Institutional Guide*'s interpretation of "risk" is broad. A later interpretation issued by HEW limits that broadness in some respects.[10] It states,

> Regulations were not, and have never been, intended to protect individuals against the effects of research and development activities directed at social or economic changes, even though those changes might have an impact upon the individual. More particularly, they were not designed to protect against possible financial injury, which may result from alteration in the price, availability or conditions of eligibility for benefits or services offered under a governmental program.

This latest interpretation also states,

> the standard for measuring any departure from "established and accepted methods" with respect to activities designed to test the effect of social change and economic change has traditionally been intended by the department to include the range of experience of the average American in his daily life. . . . Moreover the regulations are not intended to protect individuals from the "ordinary risks of daily life".

These, then, are some of the basic considerations in the *second step* of the review process. All a reviewer must do at this stage is to determine whether a human subject may be placed at risk. Although the first step could have been delegated to an administrative staff, this second determination is a professional responsibility to be discharged by the committee or by *subcommittees*.

[9] An HEW task force conducted a survey whose data suggest that the risks of participation in non-therapeutic medical research may be no greater than those of everyday life, and in therapeutic research no greater than those of treatment in other settings. The study findings are preliminary and based on interviews with researchers, so they may not represent the actual incidence of injury that would be detected through a case-by-case analysis. See P. Condon, F. Dommel, and R. Trumble, "Injuries to Research Subjects," *New England Journal of Medicine*, September 16, 1976, pp. 650–654. See also "HEW Secretary's Task Force on the Compensation of Injured Research Subjects," Office of the Secretary, DHEW, Publication 05-77-003, January 1977.

[10] 41 Fed. Reg. 26572 (1976).

If the second step review determines that human subjects are not at risk, the review need go no further and the application should be certified as approved by the committee. If, however, it is determined that human subjects may be at risk, the review proceeds to the next stage.

The *third step* of the review process, which is a final review of projects involving subjects at risk, should, according to the *regulations*, be carried out by a quorum of the committee. The requirement of a quorum strongly suggests that subcommittee or mail review is no longer appropriate and that the committee must meet as a whole.

Such review shall determine whether:

(a) The risks are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept those risks;
(b) The rights and welfare of any such subjects will be adequately protected;
(c) Legally effective informed consent will be obtained by adequate and appropriate methods.[11]

If the human subjects are allowed to accept the risks and the research project is approved, the IRB must review the conduct of the activity at timely intervals. In addition, the IRB is required to review the procedure used to obtain the required, legally effective, informed consent.

Informed Consent

Informed consent, according to HEW's regulations, means the knowing consent of an individual or his legally authorized representative, able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(a) A fair explanation of the procedures to be followed, and their purposes, including identification of any experimental procedures,
(b) A description of any attendant discomforts and risks reasonably to be expected,
(c) A description of any benefits reasonably to be expected,
(d) A disclosure of any appropriate alternative procedures that might be advantageous for the subject,
(e) An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice.

Although the HEW regulations do not explicitly state so, informed consent implicitly means that the subject at risk be able to comprehend what is put before him. That is, informed consent should be offered to the subject at risk in a language and at a level he can understand. In addition, the subject at risk must be legally competent when he gives consent. Some would argue that he must also be legally

[11] For a general discussion of risks and benefits in research and informed consent issues, see "Experiments and Research with Humans: Values in Conflict," National Academy of Sciences, Washington, D.C., 1975.

competent during his participation in the research; otherwise he is not really free to withdraw his consent or participation at any time.

Typical categories of legal incompetents are children, prisoners, and patients in mental institutions. Some jurisdictions also recognize the concept of diminished competency. For example, an intoxicated person or a person under the influence of drugs may be considered to lack competency to give consent.

The issue has been raised whether the economically disadvantaged population is incompetent to give consent.[12] It is a popular target for experimenters and, as a result of its popularity, bears a disproportionate share of experimental risk. Barriers to consent may include lack of practice in making decisions, lack of education, information inaccurately conveyed or difficult to understand, the power roles between experimenter and subject being played out in the context of the consent decision, difficulty in articulating lifetime objectives, and difficulty in rationing between present and future consumption.

HEW's regulations permit oral or written consent. Either consent, however, cannot contain any exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, including any release of the institution or its agents from liability for negligence. The procedure used to obtain informed consent and the basis for the IRB determinations that the procedures are adequate and appropriate must be fully documented.

The documentation of consent can be one of the following three forms:

(a) A written consent document embodying all the basic elements of informed consent. This may be read to the subject, but adequate opportunity for him to read it must also be given. The subject or his legally authorized representative must sign the document.

(b) A "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his legally authorized representative. The short form must be signed by the subject or his legally authorized representative and by an auditor witness to the oral presentation and the subject's signature. Written summaries of what is to be said to the subject are to be approved by the Board; a copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent and by the auditor witness.

(c) Modification of either of the primary procedures. Granting permission to use modified procedures imposes additional responsibility upon the Board and the institution to establish that:

(1) The risk to any subject is minimal,
(2) Use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and
(3) Any reasonable alternative means for obtaining these objectives would be less advantageous to the subjects.

The Institutional Guide recognizes that some studies depend upon stored data

[12] P. Brown, "Informed Consent in Social Experimentation: Some Cautionary Notes," in *Ethical and Legal Issues of Social Experimentation*, A. Rivlin and P. M. Timpane (eds.), The Brookings Institution, Washington, D.C., 1975.

or information obtained for purposes other than the research under review. In this situation, the review "should also determine whether the use of those materials is within the scope of the original consent, or whether consent can be obtained."

Educational Research

The May 30, 1974 announcement that made final the adoption of the rules regarding IRBs contained a reference to educational research. It stated,

> With respect to programs administered by the Office of Education and the National Institute of Education this part [IRB rules and regulations] shall become effective upon adoption or implementation in regulations issued by, respectively, the Commissioner of Education and the Director of the National Institute of Education, with the approval of the Secretary of Health, Education, and Welfare.

A search of the Code of Federal Regulations and The Federal Register has, however, not identified any implementing regulations that can be considered a follow-up of the May 30, 1974 announcement.

Some regulations were issued later (on November 4, 1974) by the National Institute of Education and concerned data collection instruments and the protection of human and animal subjects, but the evidence suggests that they are not related to the May 30, 1974 announcement.[13] For example, HEW's human subject regulations are issued under the authority of 42 U.S.C. 2891-3(a), the National Research Act, and the authority for NIE's regulations is 20 U.S.C. § 1221e, the General Education Provisions Act. In addition, NIE's regulations refer to HEW's policy on the treatment of human subjects and cite 41 C.F.R. § 3-4.55, the regulations that deal with procurement contracts involving human subjects, rather than 45 C.F.R. Part 46, HEW's regulations on human subjects issued on May 30, 1974. Nevertheless, a good argument can be made that NIE's regulations "impliedly incorporate" HEW's regulations on human subjects because NIE's and HEW's intent is to carry out existing HEW policy on the protection of human subjects.

The NIE regulations are a blend of the Federal Reports Act and HEW policy on the protection of human subjects. For purposes of the regulation, a data-collection instrument means tests, questionnaires, inventories, interview schedules or guides, rating scales, and survey plans or any other forms used to collect information on substantially identical items from ten or more respondents. The regulation, however, is not applicable to instruments that deal solely with (1) functions of technical proficiency, such as scholastic aptitude, school achievement, and vocational proficiency; (2) routine demographic information; or (3) routine institutional information.

Grantees are not required to submit data-collection instruments to the OMB Director or obtain the Director's approval for the use of these instruments, except where the notification of grant award specifically so provides. A grantee shall not in any way represent or imply (either in a letter of transmittal, in the data-gathering instruments themselves, or in any other manner) that the information is being collected by or for the federal government or any of its subdivisions. Basic responsibility for the study and the data-gathering instruments rests with the grantee.

[13] 45 C.F.R. Part 1410 (1976).

In any survey using data-collection instruments in which children are respondents, the grantee must assure the Director that informed consent will be obtained from each such respondent's parents before the use of such instruments, but the Director may grant a waiver for specific data-collection activities if the grantee submits a written request and justification therefor. Here a "child" means an individual who has not attained the legal age of consent, and "respondent" means individuals or organizations from whom information is collected.

Insofar as their proposal involves research with human subjects, all grantees must ensure that human subjects' rights and welfare are maintained. They must take every precaution to protect human subjects from physical, psychological, or sociological harm, in accordance with HEW's policy. In addition, no data-collection instruments shall be used that constitute unnecessary or offensive intrusions of privacy through inquiries regarding such matters as religion, sex, race, or politics.

Prisoner Research

In the May 30, 1974 announcement of the adoption of the human subject regulations, HEW also stated that future rulemaking proposals regarding the protection of human subjects would be forthcoming in the areas involving the prisoner, the child, the fetus, the abortus, and institutionalized individuals. On August 23, 1974, HEW rules were proposed for such research.[14] The details of the proposed rules will not be discussed because, with one exception, they have not been adopted.

On August 8, 1975, HEW announced the adoption of that portion of the regulations concerning research on fetuses, pregnant women, and in-vitro fertilization.[15] Rules and regulations on research regarding children, prisoners, and the mentally disabled are still in the proposed stage.

The major impetus for final adoption of rules and regulations on fetuses, pregnant women, etc. was pressure from the research community since Sec. 213 of the National Research Act had prohibited research on a living human fetus (before or after the induced abortion of the fetus unless it was done for the purpose of assuring the survival of the fetus). In carrying out Sec. 213, HEW had, therefore, declared a moratorium on fetal research.[16] The final adoption of rules and regulations on fetal research ended that moratorium. Prisoner research remains governed by the IRB regulations common to all HEW-sponsored research, the FDA regulations on new drug research,[17] and if the research is funded by LEAA, the LEAA research regulations.[18]

Recently the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a report on prisoner research, *Report and Recommendations: Research Involving Prisoners.*[19] Prisoner research is predominantly pharmaceutical research, and most of the *Report and Recommendations* was devoted to that subject.

[14] 39 Fed. Reg. 30648 (1974).

[15] 40 Fed. Reg. 33526 (1975).

[16] 39 Fed. Reg. 30962 (1974).

[17] 21 C.F.R. § 130 (1973); see also Note, *Medical and Psychological Experimentation on California Prisoners*, 7 *U.C. Davis Law Review* 351–384, 1974 and Note, *Non-Therapeutic Prison Research: An Analysis of Potential Legal Remedies*, 39 *Albany Law Review* 799–825, 1975.

[18] See below, p. 19.

[19] 42 Fed. Reg. 3076 (1977).

The first recommendation is, however, directed at social science research:

> Studies of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons may be conducted or supported. *Provided* that (A) they present minimal or no risk and no more than mere inconvenience to the subjects and (B) the requirements under recommendation (4) are fulfilled.

Recommendation (4) requires the head of the responsible federal agency to determine that the investigators are sufficiently competent and the research facilities are adequate for the research to be undertaken. Furthermore, all research involving prisoners should be reviewed by at least one human subjects review committee or institutional review board composed of men and women of diverse racial and cultural backgrounds, including prisoners or prisoner advocates and such others as community representatives, clergy, behavioral scientists, and medical personnel not associated with the conduct of the research or the penal institution.

The Commission's comments on its first recommendation stated that studies of prisoners consisting of questionnaires, surveys, analyses of census and demographic data, psychological tests, personality inventories, and the like rarely involve risk and are essential for proper understanding of prisons and their effects. Research designed to determine the effects on general health of institutional diets and restricted activity, and similar studies that do not manipulate bodily conditions (except innocuously—e.g., obtaining blood samples) but merely monitor or analyze such conditions, also present little physical risk and are necessary to gain some knowledge of the effects of imprisonment, according to the Commission's perspective.

HEW has recently issued new proposed prisoner research regulations that take into consideration its earlier proposed rules, the Commission's report, and the relevant comments submitted with respect to the earlier proposed rules and the report.[20] These regulations closely parallel the Commission's recommendations with the important difference that HEW has defined "prisoner" more broadly. For the purposes of their regulations a prisoner is

> any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing.

HEW took notice of the Commission's finding that research on prisoners is not conducted in countries outside the United States, that such research is already prohibited in all federal prisons, that it has been prohibited in eight states, and that it is conducted in only seven of the states that either permit it or do not regulate it. As a result, the HEW regulations, if adopted, would be rather restrictive of biomedical research but less so for the social science research outlined in the Commission's first recommendation.

The proposed regulations would also affect the IRB in that they require at least one member to be a prisoner or prisoner advocate. Where a particular research

[20] 43 Fed. Reg. 1050 (1978).

project is reviewed by more than one IRB, only one Board need satisfy this requirement.

Research Involving Children

When the National Research Act creating the Commission for the Protection of Human Subjects was signed into law, one of the charges to the Commission was to study the nature of research involving children, the purposes of such research, and the steps necessary to protect children as subjects. A report containing the results of such a study and the Commission's recommendations has recently been issued.[21] Unfortunately, from the perspective of the social scientist, the Commission's report focuses largely on biomedical models of research that present increasing levels of risk. Social science and educational research is minimally addressed, although the Commission's own report found that 56 percent of federal research projects involving children are supported by HEW's Education Division, and that percentage of projects accounts for 66 percent of all federal funding spent on research involving children. Nevertheless, the Commission's recommendations indicate the type of regulations likely to be adopted by HEW, so those aspects of the report most relevant to social science research are set forth.

One recommendation was that research that does not involve greater than minimal risk to children may be conducted or supported provided an IRB has determined that: (a) the research is scientifically sound and significant; (b) adequate provisions are made to protect the privacy of the children and their parents, and to maintain the confidentiality of data; (c) subjects will be selected in an equitable manner; and (d) adequate provisions are made for the assent of the children and permission of their parents or guardians.

Minimal risk is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical or psychological examination of healthy children. The Commission states,

> Many routine tools of behavior research, such as most questionnaires, observational techniques, noninvasive physiological monitoring, psychological tests and puzzles, may be considered to present no more than minimal risk. Questions about some topics, however, may generate such anxiety or stress as to involve more than minimal risk.

The Commission stated that overutilization of any one group of children based solely upon administrative convenience or availability of a population living in conditions of social or economic deprivation should be avoided. The Commission felt that the burdens of participation in research should be equitably distributed among the segments of our society, no matter how large or small these burdens may be.

The involvement of children in research has always raised questions about what constitutes informed consent in that situation. Traditionally, for their protection, children have not been considered capable of giving an informed consent. Just as traditionally, parents and guardians have had the authority to consent for the child. However, recent concern over the rights of and respect for children has

[21] 43 Fed. Reg. 2084 (1978).

resulted in the Commission's adopting a variation of the traditional informed consent.

For a child to be involved in research, the researcher should solicit both the assent of the child, if the child is 7 years or older, and the permission of the parents. The child therefore has some input. Generally his objection to participation should be binding unless the intervention may provide a direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

"Assent" rather than "consent" is used to distinguish a child's agreement from a legally valid consent. Parental or guardian "permission," rather than "consent," is used to distinguish what a person may do autonomously (consent) from what one may do on behalf of another (grant permission). Documented permission of one parent or guardian is sufficient for research of no more than minimal risk.

Recall that the Commission recommended allowing research on children only if an IRB has determined that the research is scientifically sound and significant. In the Commission's words:

> Respect for human subjects requires the use of sound methodology appropriate to the discipline. The time and inconvenience requested of subjects should be justified by the soundness of the research and its design, even if no more than minimal risk is involved. In addition, research involving children should satisfy a standard of scientific significance, since these subjects are less capable than adults of determining for themselves whether to participate. If necessary, the IRB should obtain the advice of consultants to assist in determining scientific soundness and significance.

This requirement appears to give a role and function to the IRB that neither the Commission nor HEW regulations have previously set forth. That is, the IRB now appears to become a technical reviewer of proposed research rather than a procedural and ethical reviewer. The IRBs would have to expand their concern from the protection of human subjects to a judgment concerning the validity or even desirability of a proposed avenue of research.

It is questionable whether IRBs have the ability, resources, or willingness to undertake this role. In many research organizations, technical review and IRB review are separate and the quality of each might suffer if they are to be done together. It is true, indeed unavoidable, that an IRB review requiring a determination of whether the benefits outweigh the risks of some proposed research may implicitly include a weighing of the soundness and significance of that research. Nevertheless, making that activity an explicit requirement even for minimal risk research, which includes social science research, substantially enlarges the IRB's jurisdiction.

The Commission's recommendations are not yet HEW's regulations. So the preceding discussion serves only as a preview of the issues and what the eventual regulations might be like.

Social Science Research

The May 30, 1974 announcement by HEW stated, "Policies are also under consideration which will be particularly concerned with the candidate for psychosurgery, the candidate for sterilization and, *separately, with the subject of social*

science research." To date no announcement of regulations or proposed regulations concerning social science research has been made by HEW.

The Commission's first recommendation regarding prisoner research is a clue to what it may someday advise HEW concerning social science survey research. The Commission felt that questionnaires, surveys, analyses of census and demographic data, psychological tests, personality inventories, and the like "rarely involve risk." This still does not provide guidance for the interventionist social science experiment such as an insurance, housing, or educational voucher experiment. However, one of HEW's interpretations of the human subject regulations stated that they "were not intended to protect individuals against the effects of research and development activities directed at social or economic changes, even though those changes might have an impact upon the individual."

ERDA REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS

The Energy Research and Development Administration (ERDA)[22] also has regulations in effect that protect human subjects participating in research funded by ERDA.[23] On November 30, 1976, ERDA adopted previously proposed regulations[24] relating to the protection of human subjects in research, development, and related activities supported by ERDA agreements. In this case "agreement" means a grant, contract, cooperative agreement, or any other instrument under which ERDA provides funds *or other resources* for projects or efforts involving human subjects.

The policies and procedures provided by the proposed regulations are substantially the same as those adopted by HEW (discussed in the preceding section). The regulations will be applicable to ERDA agreements supporting research, development, and related activities within the United States and its territories. For agreements supporting activities outside the United States and its territories, the regulation will apply to the maximum extent practicable as determined by the Administrator on a case-by-case basis, taking into account the relevant laws and practice of the foreign nation where the research will be conducted. "Administrator" means the Administrator of ERDA or any other officer or employee of ERDA to whom authority has been delegated.

[22] ERDA has now been incorporated into the Department of Energy.
[23] 41 Fed. Reg. 52434 (1976), 10 C.F.R. Part 745 (1977).
[24] 41 Fed. Reg. 34778 (1976).

IV. REGULATING THE STORAGE AND DISCLOSURE OF DATA

HEW HUMAN SUBJECT REGULATIONS

Except as otherwise provided by law, information in the records or possession of an institution acquired in connection with an activity covered by HEW's regulations on the protection of human subjects, and referring to or able to be identified with a particular subject, may not be disclosed except with the consent of the subject or his legally authorized representative or as may be considered necessary by the HEW Secretary to carry out his responsibilities under the HEW human subject regulations.

The clause "except as otherwise provided by law" allows disclosure of identifying information under legal process. A recent case in California, however, limited the discovery of research information obtained under a pledge of confidentiality[1] and thus may have laid a foundation for limits on disclosure of research information under legal process. In that case, the plaintiff, Richards of Rockford, brought a breach of contract and defamation action in which it appeared that a professor (Marc Roberts of the Kennedy School at Harvard), as part of a research project, had conducted confidential interviews with employees of the defendant, Pacific Gas & Electric. The court held that plaintiff's interest in satisfying its discovery request with respect to the interview notes and the identity of the employees interviewed was outweighed by the public interest in maintaining a confidential relationship between academic researchers and their sources. Thus the discovery motion was denied on the basis of the court's supervisory powers over discovery where, among other things, the information sought was largely supplementary and there was no evidence that the plaintiff was defamed during the interviews.

The decision was not based on a confidential privilege such as the attorney-client, priest-penitent, doctor-patient, or husband-wife privilege.[2] And it was not based on First Amendment grounds, as some of the journalists-informant cases have been. Rather it was based on the court's supervisory powers, which leave this type of decision largely to judicial discretion.[3]

LEAA RESEARCH

The Law Enforcement Assistance Administration has issued federal regulations governing confidentiality of research and statistical information collected in

[1] *Richards of Rockford v. Pacific Gas & Electric*, 71 F.R.D. 388 (1976).

[2] In another celebrated case, *United States v. Doe (Appeal of Samuel L. Popkin)*, 460 F.2d 328 (1st Cir. 1972), *Cert. denied, Popkin v. U.S.*, 411 U.S. 909 (1973), the Court of Appeals declined to recognize a researcher's privilege.

[3] For an interesting discussion regarding a proposed statute that creates a researcher privilege, see "Protecting Individual Privacy in Evaluation Research," The Committee on Federal Agency Evaluation Research, Assembly of Behavioral and Social Sciences, National Research Council, National Academy of Sciences, Washington, D.C., 1975. In particular, see App. B by P. Nejelski and H. Peyser, "A Researcher's Shield Statute: Guarding Against the Compulsory Disclosure of Research Data."

LEAA-funded projects.[4] These regulations were adopted to carry out Sec. 524(a) of the Omnibus Crime Control and Safe Streets Act,[5] which provided, among other things, that research and statistical information identifiable to a private person may be used only for the purpose for which obtained. The major objective of the LEAA regulations is to protect the privacy of subjects included in LEAA-funded research and statistical projects. Of equal importance, the regulations clarify the duty and responsibility of research investigators supported under LEAA *grants* and *contracts*.

The regulations apply to research or statistical information—any information collected during the conduct of a research or statistical project and intended to be used for research or statistical purposes. The term includes information collected directly from the individual or obtained from any agency or individual having possession, knowledge, or control thereof. The regulations do not apply to any records from which identifiable research or statistical information was originally obtained nor do they apply to "intelligence-information" pertaining to specific individuals and obtained for purposes directly related to enforcement of the criminal laws. Neither do they apply to information gained regarding future criminal conduct.

Any application for LEAA research assistance must be accompanied by a Privacy Certificate ensuring compliance with the regulations and establishing procedures to guarantee privacy and confidentiality. Upon completion of a research project, the regulations require the complete physical destruction of all copies of identifiable research and statistical information after a three-year required recipient retention period (or as soon as authorized by law) or removal of identifiers from the data and separate maintenance of a name-code index. Most important, the regulations provide that *copies* of research and statistical information identifiable to a private person shall be *immune from legal process* and shall be admitted as evidence or used for any purpose in any action, suit, or other judicial or administrative proceeding only with the written consent of the individual to whom the data pertain.

Original records of research and statistical information are apparently not immune from judicial or administrative subpoena. The commentary following the Federal Register announcement of the regulations stated, "It should be noted that such immunity is specifically limited to copies of information." To some extent the distinction between copies and originals made by the regulations (and the authorizing legislation) seems to reduce the protective intent of the legislation. However, retention of the original record is not required, so the original records could be destroyed to protect the information from administrative or judicial subpoena.

There is no immunity from *legislative* subpoena for original records or for copies. Thus, any legislative body could subpoena the research information and make it widely available by entering it into a public record.

The regulations require that any person from whom information identifiable to a private person is to be obtained directly (orally, by questionnaire, or by other written documents) be advised that the information will be used or revealed only for research and statistical purposes, and that compliance with the request for

[4] 41 Fed. Reg. 54846 (1976), 28 C.F.R. Part 22.

[5] 42 U.S.C. § 3701 et seq.

information is entirely voluntary and may be terminated at any time. Where findings in a project cannot, because of sample size or uniqueness of subject, be expected to totally conceal subject identity, an individual shall be so advised.

PRIVACY ACT OF 1974 [6]

The Privacy Act contains provisions to safeguard individual privacy from the misuse of *federal records*, to provide that individuals be granted access to records concerning them that are maintained by federal agencies, and to establish a Privacy Protection Study Commission. The Act places the principal responsibility for compliance with its provisions on the federal agencies but also provides that the Office of Management and Budget shall "develop guidelines and regulations . . . and provide continuing assistance to and oversight of the implementation of" the operative provisions of the Act by the agencies.

On July 9, 1975, OMB published Circular No. A-108, the guidelines for the Privacy Act.[7] The provisions of that Circular became effective on September 27, 1975. HEW had also published notices of proposed rulemaking,[8] and those rules became effective on October 8, 1975.[9]

There are several levels of documents for guidance in interpreting Privacy Act requirements: the Privacy Act, OMB's guidelines, and the implementing regulations by the relevant agencies. There might be another level, depending on the agency involved. For example, in its implementing regulations HEW authorized components of its department to issue supplementary regulations in cases where procedures are mandated by other statutes. In addition, components may issue supplementary regulations to meet particular needs of programs they administer.

The Privacy Act intends to protect federal records, so the Act might affect contractors' research in that the accessibility of federal records is restricted. This restriction may not have a practical effect on such research for several reasons. First, it would apply only where the federal contractor depends on the federal agency for the data. Second, only data subject to the Privacy Act are restricted from disclosure. There are implied exceptions to the Privacy Act—i.e., information that is *not* "contained in a system of records." And there are express exceptions to the Privacy Act—i.e., Sec.(b)(5) "to a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable." The inability to transfer individually identifiable records may, of course, limit opportunities for some longitudinal studies.

Federal contractors' major concern has not been with the accessibility of federal records but with whether records collected through their own efforts are subject to the Privacy Act's provisions as a result of their being a grantee or contractor to a federal agency. A second related issue is whether a federal contractor is subject to

[6] P.L. 93-579, 5 U.S.C. § 552a (1974).

[7] 40 Fed. Reg. 28948 (1975).

[8] 40 Fed. Reg. 34129 (1975) and 40 Fed. Reg. 41140 (1975).

[9] 40 Fed. Reg. 47406 (1975). To assist the layman, Congress has issued "A Citizen's Guide on How To Use the Freedom of Information Act and the Privacy Act in Requesting Government Documents," H.R. Rep. No. 95-793, 95th Cong., 1st Sess. (1977).

the Privacy Act's provisions as a result of its possession of federal records obtained pursuant to the research grant or contract. For purposes of the discussion of these two issues, it will be assumed that the records created by a federal contractor or the federal records in its possession would be subject to the Privacy Act if these records were created by or in possession of a federal agency. The only question then is whether those same records are subject to the Privacy Act when in the contractor's possession.

As has been mentioned before, the Privacy Act applies to records of federal agencies. Subsection (m) is an attempt to expand the applicability of the Act to contractors of a federal agency:

> (m) Government Contractors.—When an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish an agency function, the agency shall, consistent with its authority, cause the requirements of this section to be applied to such system. For purposes of subsection (i) of this section any such contractor and any employee of such contractor, if such contract is agreed to on or after the effective date of this section, shall be considered to be an employee of an agency.

On its face the provision does not appear to apply to records created by federal contractor research and it does not appear applicable to federal records under a federal contractor's research possession because such contracts are for research and not "to accomplish an agency function." Additionally, such research contracts would not be "for the operation by or on behalf of the agency of a system of records." Subsection (m) implies coverage of contracts other than research contracts. It appears to concern situations where the contractor acts as a substitute for the agency in an administrative capacity. Research, it could be argued, is rather remote from an agency function; consequently, records created or possessed in furtherance of research would be difficult to categorize as operating a system of records to accomplish an agency function. A narrow reading of subsection (m) might exclude federal contractor research activity from the Privacy Act; and, in fact, it is the opinion of the Assistant General Counsel of OMB that subsection (m) provides words not of inclusion but in strict limitation of the Privacy Act.[19] The OMB guidelines, in affirming this view, state that the "agency function" language was "intended to limit the scope of the coverage to those systems actually taking the place of a federal system which, but for the contract, would have been performed by an agency and covered by the Privacy Act."

Additionally, a contract subject to subsection (m) "would normally provide that the contractor operate such a system formally as a specific requirement of the contract." Arguably, federal research contracts do not undertake to operate a system of records as a contract requirement. Normally a researcher operates a system of records as a result of research discretion in using a number of different methodological approaches. The operation of such a system is often not a contract requirement but a research choice. In fact, the OMB guidelines state that the subsection (m) language that the contract provide for the operation of a system was intended "to avoid covering a contractor's system used as a result of the management discretion."

[19] R. Bedell, "Government Contractors and the Initial Steps of the Privacy Act," 34 *Federal Bar Journal* 279 (1975).

According to OMB's Assistant General Counsel, "A contract for the design, maintenance, or the operation of any service associated with the system other than operations does not bring the contract within subsection (m)." There may be few practical effects of the legal distinctions because the Assistant General Counsel also said,

> This is not to say, however, that contractors who design or provide maintenance on systems of records, and the agencies with whom they contract, can ignore the Privacy Act. Although such contractors may not be covered by subsection (m), they must insure that such systems are designed to be operated in conformance with the Act, and will, of course, be subject to the disclosure restrictions in the Act.

Thus far the discussion has been about whether subsection (m) is applicable to federal research contracts. Research is also done under grants, and the question arises whether a grant is to be treated as a contract for subsection (m) purposes. It has been suggested that both will receive the same treatment because the acceptance of a grant can be looked upon as establishing a contractual relationship and because the potential threat to individual privacy is equivalent to that posed by a contract.

This is an arguable point. A grant need not create a contractual relationship. Although the threat to privacy may be equivalent, the Act does not cover many other equivalent threats. The HEW Privacy Act regulations expressly exclude grants from their applicability. The omission in the Privacy Act therefore seems purposeful because Congress was concerned with initially limiting the Act's applicability as much as possible.

The omission of grants might indicate a purpose to exempt research activities from the provisions of the Act. Grants are not given for "the operation of a system of records to accomplish an agency function"; grants are generally given for research. This latter interpretation would also be consistent with the exemption in subsection (b)(5) for a "statistical research or reporting record."

OMB's guidelines also state that "Contract" covers "any contract, written or oral, subject to the Federal Procurement Regulations (FPRs) or Armed Services Procurement Regulations (ASPRs)." The FPRs and ASPRs also have grant provisions, so OMB has apparently again explicitly excluded grants from the Privacy Act's purview.

In short, there is serious doubt whether subsection (m) applies to general federal research contracts and therefore whether a federal research contractor is subject to the Privacy Act. Such a contractor may nevertheless wish to set up privacy protection procedures equivalent to those required of the federal agencies (or more stringent ones) as a matter of its own policy or in the expectation that at some future date the Privacy Act will be applicable.

Subsection (m) may be applicable to a federal research contractor in two special cases. One is when that contractor is a federal contract research center (FCRC). An FCRC could be considered an employee of an agency accomplishing an agency function and may as part of the contract operate a system of records on behalf of the agency.[11] Second, a federal contractor may be subject to the Privacy Act if he

[11] The Privacy Act does not consider distinctions among federal contractors beyond whether or not they accomplish an agency function. So it could be argued with equal force that there is no explicit basis for treating an FCRC as an agency employee simply because of its FCRC status.

has access to a federal system of records on a direct-line time-sharing basis. In both cases, there may be an obligation to protect data within that system in conformity with the agency's obligations under the Privacy Act.

If the Privacy Act does apply to federal contract research records, to what specific records is the Privacy Act applicable, what are the provisions, and in what circumstances is a federal contractor relieved of the provisions of the Act?

If an organization subject to the Privacy Act maintains a system of records subject to the Privacy Act, then the Act (1) imposes conditions on disclosures, (2) requires an accounting of certain disclosures, (3) provides an individual with access to his records, (4) imposes safeguards on the use of the records, and (5) provides remedies for a breach of the Act's provisions.

To establish applicability of the Act requires definitions of "records," a "system of records," and "maintain." "Maintain" is defined by the Act as "maintain, collect, use, or disseminate." OMB's further clarification indicates that maintain is also used to connote *control* over and hence responsibility and accountability for systems of records. Maintain means having effective control, but that does not necessarily mean to have physical control. Mere access for performance audits may not constitute sufficient control over the record system to cause the Privacy Act to be applicable.

A "record" is defined as

> any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual such as a finger or voice print or a photograph.

The term "record" was defined to ensure the intent that a record can include as little as one descriptive item about an individual. A record, by this definition, can be part of another record. Therefore, prohibitions on the disclosure of a record apply not only to the entire record but also to any item or group of items from a record if that grouping contains a particular identifier.

The term "system of records" means "a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual." Most of the discussion regarding the applicability of the Act centers around this definition.

The definitions for "maintain" and "record" do not present as much difficulty because collecting, using, or disseminating fits most data manipulations and one item with an identifier can easily constitute a record. In contrast, the definition of a "system of records" is conditional as well as definitional. That is, the records must be *under the control of an agency* and the information must be *retrieved by the use of a personal identifier.*

According to the OMB guidelines, the phrase "under the control of any agency" was intended to accomplish two separate purposes: (1) to establish possession and accountability and (2) to separate agency records from records maintained personally by employees of an agency but that are not agency records. The second purpose could be used to claim that a federal contractor researcher's records are not under the control of an agency, therefore not a system of records and not subject to the

Privacy Act. For example, the OMB circular states "Uncirculated personal notes, papers, and records which are retained or discarded at the *author's discretion* and over which an *agency exercises no control or dominion* (e.g. personal telephone lists) are not to be considered agency records within the meaning of the Privacy Act."

An argument against this interpretation is that OMB's example is concerned with personal notes, papers, and records that relate more to the author's personal work than records belonging to a project. A researcher may be only part of a project and may not have the discretion to discard the project's records. However, the project researchers may, as a group, have the discretion to discard the records. Nevertheless, if an agency does not exercise control or dominion over the project's records (even if the individual researcher exercises no discretion over them) then it could be said that there is no system of records.

The "system of records" must consist of records retrieved by reference to an individual name or some personal identifier. The "retrieved by" criterion implies that an agency can access the grouping of records under its control by use of a personal identifier, not merely that there is a capability or potential for retrieval.

Interdepartmental memoranda at HEW[12] make a distinction the OMB guidelines do not mention. HEW's position is that

> data sets which have personal information indexed by a code which is always blind to the user and from which personal information is not accessed or retrieved by an index which associates data with a known (i.e. identified) individual also fall outside the scope of the Act.

This view has not been codified in any HEW regulation but has been the circulated view between HEW's advisory counsel and the Office of Education (OE) and between OE and some federal contract researchers.

This view rests on the argument that if personal identification is made difficult through the use of a code that transforms a common identifying particular, such as a surname or social security number, to a less familiar identifying particular, such as another combination of letters and numbers, the individual is protected if the code is kept separate and less accessible to the routine user of the information and is used only to identify an individual from whom additional data are requested.

This view is challengeable on several counts. First, the use of a code does not remove the identification of a record—it just assigns a different identifying symbol. The definition of a "system of records" anticipates the use of codes by expressly mentioning information "retrieved by the name of an individual or by some *identifying number, symbol* or other *identifying particular*." Second, keeping the code separate and less accessible to the routine user only makes the ultimate personal identification more remote but does not change the fact that information is being routinely accessed by an identifying particular whether through the use of one code or several codes. Third, if HEW's view were to be valid, the purpose of the Privacy Act would be frustrated because an agency could then use a code to take records out of the Privacy Act's purview. As a result, an individual could not invoke the Privacy Act's protection restricting disclosures of his records, requiring an accounting of who looks at his records, being allowed access to view his records, having the

[12] Memo to the Assistant Secretary for Education, from the Education Division Privacy Task Force, Subject: Operating Definition of System of Records, DHEW, Education Division, September 4, 1975.

opportunity to rebut erroneous entries, and having a remedy for breaches of the Act.

HEW's view is unfortunate in that codes are one method of safeguarding data privacy, which is one of the purposes of the Act. Ironically, HEW uses that safeguard to argue inapplicability of the Act. It is doubtful that HEW's position has validity, or else the citizenry is one code away from the world, as it was before the Privacy Act. The evil to be guarded against is not the existence of data that are retrievable by an individual identifier, and it is not the retrieval of information by a primary or secondary individual identifier; rather it is the retrieval of information by *any* identifying particular assigned to the individual.

Assume now that a federal contractor is subject to the Privacy Act, that some of its research records are systems of records subject to the Act, and that as a result such a contractor becomes an "Agency" for the purposes of the Act. What would be the contractor's obligations?

With respect to disclosure, there would be a general prohibition on disclosure without written consent by the individual concerned. The exceptions to the rule are listed in subsection (b), of which the exceptions applicable to a federal contractor would be: (1) those officers and employees of the contractor that maintains the record who need the record in the performance of their duties, (2) a request under the Freedom of Information Act, (3) a routine use, and (4) a recipient who has provided the contractor with adequate advance written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable.

Except for disclosures under (b)(1) and (b)(2), the federal contractor would have a duty to keep an accounting of the data, nature, and purpose of each disclosure and the name and address of the person or agency to whom the disclosure is made. The accounting would have to be retained for five years and would be accessible to the individual named in the disclosure. The contractor would have the duty of informing the recipient of disclosed information about any correction or dispute of any record disclosed.

A contractor would also have the duty to allow an individual access to his record, to permit him and an individual of his choosing to accompany him to review the record and to have a copy made. The individual would have a right to request an amendment to the record and to have a correction or response to that request within ten days. A contractor could, however, refuse amendment of the record but would have to provide for a review of that refusal. If no amendment is finally made, an individual would have the right to know the reasons why and to file a statement of his reasons for disagreement with the refusal to amend.

Subsection (e) of the Privacy Act imposes extensive safeguards on information contained in a system of records. It includes indexing of all systems of records, public notice of their existence, permissible contents of those records (i.e., no records describing the exercise of First Amendment rights are allowed), and the establishment of rules of conduct for persons involved in the design, development, operation, or maintenance of any system of records.

The many requirements that would be imposed make it questionable whether the Act was intended to apply to federal research contractors. If the Privacy Act reaches federal research contractors, then it reaches most contractors to the federal agencies. However, that would be inconsistent with the intent of the Act, which appears to be limited to those few contractors accomplishing an agency function.

CONFIDENTIALITY OF ALCOHOL ABUSE RESEARCH RECORDS

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act, as amended,[13] was first promulgated as P.L. 91-616 (1970) and later amended by P.L. 93-282 (1974). It states:

> (a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation *or research*, which is conducted, regulated, or *directly* or *indirectly assisted* by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

This subsection governs accessibility to patient records and the restrictions on disclosure of any such records. Subsection (b) (1) requires a written consent prior to disclosure and refers to subsection (g), which states that "the Secretary shall prescribe regulations to carry out the purposes of the [Act]. These regulations may contain such definitions and may provide for such safeguards and procedures . . . as . . . are necessary." Subsection (b)(2) provides for disclosure without a prior written consent "to qualified personnel for the purpose of conducting scientific research . . . or program evaluation" but disallows individual identification of a patient in any report or in any other manner.

In accordance with the 1974 amendments to this Act on May 9, 1975, HEW and the Special Action Office for Drug Abuse Prevention published a notice of proposed rulemaking setting forth regulations governing the confidentiality of alcohol and drug abuse patient records.[14] The regulations as finally adopted were announced several months later[15] and became effective on August 1, 1975.

The regulations do not add much more as the Act itself is fairly explicit. However, Sec. 2.12 on Applicability does state that the regulations apply to records of research "conducted in whole or in part, whether directly or by *grant, contract,* or otherwise," by any department or agency. In contrast to the Privacy Act, which had narrow applicability, "this wording suggests an intention to provide the *broadest* coverage consistent with the literal terms of the statutes."

Section 2.52 restates that disclosure of records without consent "to qualified personnel for the purpose of conducting scientific research . . . or program evaluation" is permissible. However, this section also imposes a duty on these qualified personnel to provide "adequate administrative safeguards against unauthorized disclosures." A standard for adequate administrative safeguards is suggested in Sec. 2.17 on Security Precautions:

> (a) Appropriate precautions must be taken for the security of records to which this part applies. Records containing any information pertaining to patients shall be kept in a secure room, or in a locked file cabinet, safe, or other similar container when not in use.

[13] 42 U.S.C. 4582 (1974).
[14] 40 Fed. Reg. 20522 (1975).
[15] 40 Fed. Reg. 27802 (1975).

(b) Depending upon the type and size of the program, appropriate policies and procedures should be instituted for the further security of records.

This Act and its regulations seem reasonable and reach a good accommodation between preventing disclosures without consent and allowing disclosures without consent for research and evaluation purposes. There is, however, a potential conflict with the Privacy Act. The philosophy of the drafters of the regulations is expressed in Sec. 2.52-1(g):

> In sum, there are restraints on certain means of governmental acquisition of information about individuals which are operative irrespective of how the information is used, and there are restraints on the uses of information which are independent of how or by whom it is acquired, *but they do not add up to the proposition that the use of information about a person is either morally or legally the absolute prerogative of that person to determine.*

The drafters of these regulations do not address the requirements of the Privacy Act of 1974. The effect of the Privacy Act on these records is never mentioned in the regulations; and because the Privacy Act is later, its narrower construction will preempt these regulations whenever they are both applicable. If, as has been argued, the Privacy Act does not apply to federal contractors, then these regulations regarding the confidentiality of alcohol and drug abuse patient records will be applicable to research in this area. If the Privacy Act is applicable to federal contractors, the stricter requirements of that Act nullify regulations that allow disclosure without consent to researchers *if* the patient records are construed to be a system of records accomplishing an agency function.

FREEDOM OF INFORMATION ACT [16]

The Freedom of Information Act (FOIA) was enacted in 1966 for the express purpose of increasing public access to government records to augment popular control of government and encourage agency responsibility.[17] The FOIA replaced a policy of nondisclosure of governmental information with a policy that favored mandatory disclosure. The FOIA required that identifiable agency records be disclosed to "any person" who requests them and provided sanctions for improper withholding of information by an agency.

The FOIA, however, also contained nine exemptions from its provisions. The disclosure requirements of the FOIA do not apply to matters that are:

(1) Specifically required by Executive Order to be kept secret in the interest of national defense or foreign policy;
(2) Related solely to the personnel rules and practices of an agency;
(3) Specifically exempted from disclosure by statute;
(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

[16] 5 U.S.C. § 552 (1970).

[17] See Note, "The Freedom of Information Act and the Exemption for Intra-Agency Memoranda," 86 *Harvard Law Review* 1047 (1975).

(5) Inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency;
(6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
(7) Investigatory files compiled for law enforcement purposes except to the extent available by law to a party other than an agency;
(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or
(9) Geological and geophysical information and data, including maps, concerning wells.

Because the FOIA was passed for the specific purpose of making *federal records* available to the public, a question arises whether a federal contractor must comply with a request made by an individual for a disclosure of federal records in its possession.

If the federal contractor is in possession of records supplied by a federal agency, presumably the federal agency retains a copy of those records. If so, a request for disclosure would more properly lie with the federal government because the Act is directed at the federal agencies. It therefore seems logical that in the more removed situation where a federal contractor has records collected under federal contract but not shared with the agency, the FOIA should not apply. In an advisory letter to OE/Office of Planning, Budget and Evaluation, the attorney advisor to that office stated,

> We have consistently maintained that the Act applies only to federal records and for this reason we believe that records under the control of a government/subcontractor are not subject to its provisions. Accordingly, we believe those records . . . would not, until the court holds otherwise, be required to be disclosed under the Act.[18]

If a federal contractor collects records under federal contract and supplies or shares them with the agency, they arguably become federal records subject to disclosure by the federal agency. However, as in the case of federal records collected by federal agencies, those records are exempted from mandatory disclosure if they fall under the category of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

The issue then becomes to determine what is meant by "clearly unwarranted." That is, an individual could request information about another individual and the request for disclosure would be denied if it was a *clearly unwarranted* invasion of privacy but could not be denied if it was a *warranted* invasion of privacy or if it was *unclear* whether it was an unwarranted invasion of privacy.

At this point it would be fruitful to consider what effect the passage of the Privacy Act of 1974, 5 U.S.C. 552a, had on the disclosure requirements of the Freedom of Information Act. The quick answer is none, despite the declared pur-

[18] Letter to Dr. Ann Bezdek of OE/Office of Planning, Budget and Evaluation from Heidi A. Dellafera, Attorney Advisor, November 28, 1975.

pose of the Privacy Act to provide safeguards for an individual against an invasion of personal privacy by requiring federal agencies to "permit an individual to prevent records pertaining to him obtained by such agencies for a particular purpose from being used or made available for another purpose without his consent."[19] Section 552a(b)(2) of the Privacy Act exempts from its restrictions on disclosure any disclosure required by the Freedom of Information Act. Thus, the potential conflict between the Freedom of Information Act and the Privacy Act are resolved in the favor of the former.

The Freedom of Information Act, in general, was not applicable to federal contractor records, but records collected by a federal contractor and given to the federal agency would be subject to the Act. Therefore, if a federal contractor wished a higher standard of privacy for its records, it might reconsider whether to supply its records to a federal agency or whether it should limit the information collected if it is to be shared with a federal agency.

[19] P.L. 93-579, § 2(b)(2) (1974).

V. SANCTIONS FOR NON-COMPLIANCE

FEDERAL REPORTS ACT

Information collected under the authority of the Federal Reports Act is protected through the Act's penalty provisions for unauthorized disclosure. Sec. 3508 generally prohibits and penalizes the transfer by one federal agency and acceptance by another federal agency of information obtained under the Act, although there are some exceptions and conditions for transfer and acceptance.

The Act is silent about transfer to or disclosure by the sponsored researcher or contractor. It could be argued that because the Privacy Act of 1974 made contractors explicitly liable for some of the criminal penalties of that Act, then by implication the absence of such a provision in this Act suggests a Congressional desire not to make contractors liable.

18 U.S.C. § 1905

To what extent a federal contractor can be considered an "employee" of a federal agency is crucial to the interpretation of yet another penalty provision, 18 U.S.C. § 1905, which concerns the disclosure of confidential information. The Federal Reports Act penalty provision dealt with disclosure from one agency to another, and this provision deals with disclosure to *anyone* not authorized by law to receive such information. It provides for a maximum $1000 fine and a maximum one year in prison, or both, plus removal from office or employment for any officer or employee of the United States or any department or agency who makes an unauthorized disclosure of *confidential information.* Because this statute rests on the same issue of whether a federal contractor is an "employee" of an agency, the conclusion is also that the lack of an explicit provision making contractors "employees" would exempt a federal contractor from the penalty provisions.

HEW HUMAN SUBJECT REGULATIONS

If, in the judgment of the HEW Secretary, an institution has failed materially to comply with HEW's policy on the protection of human subjects with respect to a particular grant or contract, the Secretary may require that said grant or contract be terminated or suspended. In evaluating applications or proposals for support of activities that involve human subjects, in addition to all other eligibility requirements and program criteria HEW may take into account such factors as:

(1) Whether the applicant or offeror has been subject to a termination or suspension for failing to comply with HEW's human subject regulations.
(2) Whether the applicant or offeror or the person who would direct the scientific and technical aspects of an activity has in HEW's judgment failed materially to discharge his, her, or its responsibility for the protection of

the rights and welfare of subjects in his, her, or its care (whether or not HEW funds were involved).

(3) Whether, where past deficiencies have existed in discharging such responsibility, adequate steps have in HEW's judgment been taken to eliminate these deficiencies.

LEAA RESEARCH

Where LEAA believes that a violation has occurred of Section 524(a) of the Omnibus Crime Control and Safe Streets Act of 1968 of the regulations on the confidentiality of identifiable research and statistical information, or of any grant or contract conditions entered into, it may initiate administrative actions leading to termination of a grant or contract, commence appropriate personnel and/or other procedures in cases involving federal employees, and/or initiate appropriate legal actions leading to imposition of a fine not to exceed $10,000 against any person responsible for such violations.

"Any person responsible for violations" would include the grantee organization as well as particular individuals (including grantee employees) committing violations. Actions against federal employees will be based on 18 U.S.C. § 1905.

ALCOHOL ABUSE RESEARCH

Any person who violates any provision of the authorizing legislation, Section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, or any provision of the regulations on the Confidentiality of Alcohol and Drug Abuse Patient Records will be fined not more than $500 in the case of a first offense and not more than $5,000 in the case of each subsequent offense.

PRIVACY ACT OF 1974

If a federal contractor is considered to be a subsection (m) contractor, he would be liable to the penalty provisions specifically referred to in subsection (m). Those penalties are included in subsection (i), the criminal penalties subsection. For an unprivileged, willful disclosure by any officer or employee, there is a fine of $5,000. For violation of the notice requirements of a system of records, there is also a $5,000 fine.

It should be noted that 18. U.S.C. § 1905 specifies incarceration for an unauthorized disclosure of confidential information by an agency employee. Subsection (m) considers contractor employees as agency employees for the criminal penalties provisions. Therefore, there is a possibility that the 18 U.S.C. § 1905 penalty provisions are also applicable.[1]

Subsection (m) is confusing in one regard. It makes contractor employees specifically liable for the criminal penalties, but it also states that contractors must

[1] Greenawalt (1975), p. 107.

comply with "the requirements of this section" where "section" refers to the Privacy Act, codified in *Section 552a* of the United States code. Therefore, a question arises whether the reference to the criminal penalty provision is verbiage or is intended to exempt a contractor from the civil remedies subsection, which could expose a contractor to a much higher liability than the criminal penalty provisions.

VI. CONCLUSION

One perspective on the regulations discussed is that they parallel the information continuum from creation or collection of information to its storage and disclosure. The Federal Reports Act and the regulations protecting human subjects govern the process of information creation and collection. The Privacy Act governs manipulation and storage of information. Both the Privacy Act and the Freedom of Information Act regulate information disclosure. These categories are not exclusive and necessarily overlap, but with this perspective it is possible to recognize the concept of regulating the information *process* rather than separating its elements and forcing partial solutions to a larger problem.

These regulations were created as a result of concerns other than the regulation of social science research information. Yet the effect has been substantial. Rather than to continue further with this *ad hoc* regulation, legislators should specifically consider what public policy ought to be concerning social science research information and federal social science research contracts. Information has many uses, and unfortunately there is no consistent policy that cuts across these regulations when the information use is for social science research.